

54. (once amended) A method of providing a hematinic agent for treating a subject deficient in iron, consisting of the steps of:

formulating a composition which is a carboxymethylated reduced ultrasmall iron oxide complex; and

terminally sterilizing the composition by autoclaving.

64. (once amended) A reduced carboxyalkylated polysaccharide iron oxide complex which is stable at a temperature of about 121 °C, wherein a sodium salt of the complex does not contain an infrared absorption peak in the region of about 1650  $\text{cm}^{-1}$  to about 1800  $\text{cm}^{-1}$ .

66. (once amended) A reduced carboxyalkylated polysaccharide iron oxide complex according to claim 64, wherein the polysaccharide is carboxymethylated.

#### Remarks

Applicants express appreciation for the courtesy extended in a personal interview with Examiner Wells and Supervisory Patent Examiner Padmanabhan on September 25, 2002 and in a telephone interview on October 3, 2002, in which the pending claims were discussed. On September 25, 2002, there was filed by hand a Declaration of Jerome M. Lewis, Ph.D. in Support of Applicants' Response (copy attached hereto); this declaration shows unexpected results in relation to prior art of record.

Claims 5, 6, 21, 23, 35-36, 39-52, and 56 are canceled. Claims 1, 7, 10, 11, 12, 13, 18, 19, 20, 22, 25, 26, 27, 28, 29, 53, 54, 64, and 66 have been amended herewith in accordance with discussions with the Examiners. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attachment is captioned "Version with markings to show changes made". The number of micromoles in claim 28 is rewritten without a comma solely to improve readability of the claim, and there is no change to the claim scope or meaning in respect of this portion of the amendment. The change in claims such as 53 and 54 from "colloid" to "complex" is intended to be a broadening amendment; similar language already appeared in numerous claims, beginning with claim 1. (An analogous change in claim 29 eliminates reference to "colloidal suspension".) Certain claim dependencies have been changed to facilitate generation of dependent claims as marked in the attachment.

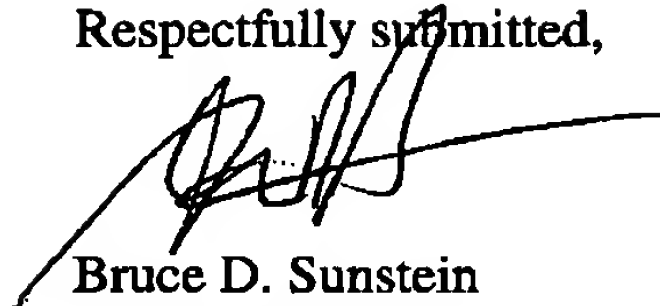
The amendments are otherwise designed to overcome pending rejections under 35 U.S.C. §§ 112 and 103. It is noted for the record that, in addition to the unexpected results adduced by the foregoing declaration, the recitation in claims 10 and 64 to the absence of an infrared absorption peak in the region of about 1650 cm<sup>-1</sup> to about 1800 cm<sup>-1</sup> (a limitation supported by the Application, for example, on page 3, lines 5-8) is in contradistinction to the characteristics of a composition analyzed in Maruno '378 (see Fig. 5 therein).

For the foregoing reasons, it is submitted that the application is now in condition for allowance. Reconsideration of the claims and issuance of a notice of allowance are

therefore respectfully requested.

Date: October 8, 2002

Respectfully submitted,

A handwritten signature in black ink, appearing to be "B. Sunstein", written over a horizontal line.

Bruce D. Sunstein  
Registration No. 27,234  
Attorney for Applicants

Bromberg & Sunstein LLP  
125 Summer Street  
Boston, Massachusetts 02110-1618  
Tel: (617) 443-9292  
Fax: (617) 443-0004